Remarks

Specification

The Examiner noted an omission at pages 15-16. In response, a replacement paragraph for page 15 is submitted and we request that the paragraph fragment on page 16 be deleted. No new matter is added by these amendments.

Support for the Claim Amendments

The amendments to the claims are supported by the application as filed; no new matter has been added. Specifically, support for administering the recited composition to a "primate" (amended claim 1) and a "human" (new claim 10) may be found may be found in Examples IHV, which teach administration to rhesus monkeys, and at page 3, lines 3-22, page 4, lines 3-35, and page 22, lines 20-27, which teach administration to humans. Support for the remaining amendments, to claims 1, 3, 4, 5, and 8, may be found in the original claims.

Claim Objections

The Examiner objected to the term "HIV virus" in claims 5 and 8. In response, these claims have been amended to recite simply "HIV," thereby obviating the objection.

§ 112 Rejections

Claim 1 has been amended to recite administration of a "composition," rather than administration of a "vaccine composition," thereby obviating the § 112 rejections.

§ 102 Rejections

The standard for anticipation is well-settled: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegall Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). In this case, neither of the two articles cited as prior art discloses each and every element of the sole

independent claim, claim 1. More specifically, neither Thibodeau et al. nor Gaffar et al. teach administration of a composition to a primate, as recited in claim 1, instead teaching administration to rabbits or hamsters, respectively. Furthermore, neither Thibodeau nor Gaffar teach the production of a local immunogenic response by administration in the floor of the mouth, or sublingually, as recited in the claims. For instance, Thibodeau teaches that an antigen was introduced "into the mouth of the animals, one drop at a time" (see page 390, line 9) and Gaffar teaches that a vaccine was "injected locally (under the chin) in golden hamsters" (see column 4, lines 19-20). Therefore, we respectfully submit that claim 1 and dependent claims 2-10 are novel over the cited art.

Moreover, neither Thibodeau nor Gaffar can serve as the basis for a prima facie case of obviousness, which requires both a suggestion of the claimed invention and a reasonable expectation of success. See M.P.E.P. § 2142 at 2100-124 (citing *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991)). First, neither Thibodeau nor Gaffar alone or in combination suggests the presently claimed method of administration to the floor of the mouth of a primate. In addition, there would not have been a reasonable expectation of success based on these references. With respect to Thibodeau in particular the specification states, at page 2, lines 31-32: "In actual fact, there are no grounds for saying that the results [seen in rabbits] can be applied to humans." Similarly, there would have been no reasonable expectation that the methods of administration to hamsters taught by Gaffar, if modified to include sublingual administration, would be successful in primates. Furthermore, neither Thibodeau nor Gaffar teaches or suggests the production of an immune response offering a double barrier of protection (IgA response in both saliva and lymph nodes), which results from the claimed method (see page 5, lines 6-11; see also Tables 1 and 3). Therefore, we respectfully submit that claim 1 and dependent claims 2-10 are nonobvious over the cited art.

§ 103 Rejections

According to the MPEP, "The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness." MPEP § 2142, p. 2100-123. "To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." *Id.* at 2100-124 (citing *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991)). Additionally, "The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done."

In paragraphs 15 and 16 of the office action, claims 1-5, 8, and 9 were rejected as being unpatentable over Thibodeau in view of four other references (Mathiowitz et al., Irwin et al., Lowell et al., and Gandhi et al.). However, as noted above with regard to the § 102 rejections, Thibodeau fails to teach sublingual administration to primates (instead teaching oral—though not sublingual—administration of an immunogenic composition to rabbits) and one would not have had a reasonable expectation that the methods taught by Thibodeau, modified as in the present claims, would succeed in primates. Moreover, none of the four secondary references compensate for the deficiencies of Thibodeau—none suggest sublingual administration to primates and none provide any teaching that would have given one of ordinary skill in the art a reasonable expectation of success. In addition, none of the five references teach or suggest administration to the floor of the mouth of a primate to produce an immunogenic response in both saliva and lymph nodes, as results from the presently claimed method.

The Examiner also rejected claims 1-5, 8, and 9 as obvious over Hinkula et al. in view of Irwin and Beckenkamp, and further in light of Kozlowski et al. and Gorse et al. However, Hinkula, the primary reference, fails to teach or suggest methods involving administration of an antigen to a primate, instead limiting its disclosure to mice. In addition, more than failing to teach administration to the floor of the mouth (as the Examiner conceded), Hinkula and at least one secondary reference actually teach away. For example, Hinkula focuses on intranasal administration, virtually ignoring oral administration. See, for example, page 887, columns 1 and 2. Furthermore, while asserting that Beckenkamp indicates that cells in the floor of the mouth produce IgA, the Examiner conceded that Beckenkamp teaches that "the floor of the mouth is not the most responsive region in the mouth." Thus, Hinkula and the cited secondary references fail to suggest the instantly claimed methods. Likewise, Hinkula and the cited secondary references fail to show that one of skill in the art would have reasonably expected the claimed methods to be successful.

Finally, claims 1-5, 8, and 9 were rejected under § 102(e) as anticipated by or, in the alternative, under § 103(a) as obvious over Becker et al. (U.S. Patent 6,379,675) in view of Gorse and Beckenkamp. However, like Hinkula, the teaching of Becker is limited to mice, and includes no teaching or suggestion of administration to the floor of the mouth. Indeed, Beckenkamp teaches away from oral administration altogether. Furthermore, neither Becker nor the secondary references show that one of skill in the art would have reasonably expected that the claimed methods would be successful at producing the observed immune response in primates.

Accordingly, we respectfully submit that a prima facie case of obviousness has not been established.

Conclusion

In view of the foregoing, the applicant respectfully requests reconsideration and withdrawal of the pending § 112, § 102, and § 103 rejections. If there are any questions or comments regarding this Response or application, the Examiner is encouraged to contact the undersigned attorney as indicated below.

Respectfully submitted,

Date: February 4, 2004

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